

HEMOPHILIA ADVISORY BOARD

Minutes of the March 22, 2010 Meeting

Members Present

Tracy Cleghorn
Laura Duncan
Sheila Elliott
B. Gail Macik
Craig Smith (speaker phone)
Eric Werner

Members Absent

Sylvia Richendollar

Interested Parties

Nancy Bullock
Paul Brayshaw
Nicholas Cady
Rachel Cain
Lauren Dunn
Ryan Faden
Janet Fox
Mike Herbert
Mindy Nolte
Kim Stewart
Kate Lynch
Kelly Waters

Staff

Jan Kuhn
Candice Robinson

I. Introduction of members and general business

The meeting was called to order at 10:15 a.m. A membership list was distributed for revision. Jan Kuhn introduced Laura Duncan and Sheila Elliott, two new members of the Board representing the general public and pharmacies respectively. Jan reported that she received conflict of interest disclosure statements for all of the board members in January. Candice Robinson reviewed the method to complete the on-line conflict of interest training. She will also send the members the login steps and website link. The Board reviewed their bylaws and did not make any changes at this time.

II. Minutes

As recommended by the Board at their December 8, 2008 meeting, the minutes of this meeting will be disseminated shortly after the meeting for review with a sunset date for comments. The minutes will be posted by 30 days from this meeting.

III. Annual Virginia Bleeding Disorders Program (VBDP) Update

Jan began the program report with a review of the agenda as the items related to the core functions of public health and the goals of the Maternal Child Health Bureau. She reported that the new contracts to the hemophilia treatment centers (HTCs) would

include reporting on their family satisfaction surveys, the annual hemophilia data set and the Region III Monitoring Survey. She then discussed current program enrollment statistics, with comparisons to last year's report where significant. In fiscal year 2009, the program served 275 patients (2008: 259). Most of the patients on the program have either severe or moderate Factor VIII Deficiency. The percentages by gender, diagnosis and clinic have remained similar to 2008. She noted that the percentage of patients is slightly lower from Children's Hospital of the King's Daughters (CHKD) and noted that she is working with the team to increase enrollment. The strategies to-date include a chart review with the nurse coordinator and the inclusion of the center social worker on insurance case management quarterly calls. The clinic is now holding bimonthly rather than weekly clinics with higher number of patients per clinic. This may allow the VBDP coordinator to see more patients on monthly visits. Jan then presented a more detailed report on patients by insurance, identifying twenty-seven percent of the patients on Medicaid/FAMIS, fifty-four percent on private insurance, nine percent on Medicare and nine percent uninsured. Sixteen patients used Pool of Funds (POF) in fiscal year 2009 with 74% uninsured (increased from 67% in 2008), 12% capped (11% in 2008) and 13 having a pre-existing condition (22% in 2008). Further details about POF were presented later.

Candice Robinson and Jan then presented the results of the family satisfaction survey, mailed to 234 families in September 2009, with a 22% response rate. Eighty-seven percent of the respondents reported that they had health insurance and fifty-six percent of these reported that the costs were always or usually reasonable. Only two percent reported that their health insurance does not allow them to see health care providers needed to manage their hemophilia care. Gail Macik questioned whether this could be related to the military restrictions. Eric Werner mentioned that some military patients that seek medical care at Portsmouth Naval are not referred to an HTC unless surgery is needed. He noted that more outreach may be necessary. Kelly Waters reported that some patients on one insurance carrier in Northern Virginia have complained about lack of HTC access. Eighty-two percent were very satisfied or somewhat satisfied with coordination of care (13% did not respond); 50% very satisfied or somewhat satisfied with the services of the state pharmacy (44% did not respond), and 68% were very satisfied or somewhat satisfied with the services of PSI (27% did not respond). Lack of responses to some of the questions may be related to lack of use of these services. Other themes from open-ended questions include concerns about HTC funding, the need for increased dissemination of information and concerns about restrictions placed by their insurance companies on providers.

IV. Patient Services Incorporated (PSI) Presentation

Janet Fox from PSI presented their annual report. She discussed the number of clients served in the past year and presented trend data since 1996. She also discussed the cost avoidance to the state for patients who receive case management and premium assistance through PSI. She discussed the new PSI policies that were implemented in July of 2008 and the VBDP/PSI policy changes approved by the HAB in March of 2009, taking effect in July of 2009. She reviewed the numbers of patients transitioning off of

PSI assistance and the reasons for no longer needing PSI services. Janet discussed that funding constraints would prevent PSI from providing in-kind funding in 2010. Additionally, she discussed new legislative efforts for funding. Janet also discussed the additional programs available to bleeding disorder patients, including the Advocating for Chronic Conditions, Entitlements and Social Services (ACCESS) program which assists patients with disability determination. Jan commented that status of disability determination for patients referred by the HTC or VBDP to ACCESS is now discussed at quarterly conference calls, maintaining the lawyer-client privilege.

V. Program Budget and Pool of Funds Trends

Jan presented an overview of the trends in Pool of Funds utilization in the past three years. She noted that, as discussed last year, the POF is increasingly utilized for patients from the ages of 19-35 years of age, for patients with severe disease and for patients who are uninsured without a clear plan for acquiring insurance. Jan discussed the strategies implemented in 2009 to reduce POF costs. These limited to outpatient factor coverage to \$15,000 and total per patient caps at \$50,000. Additionally, the HAB agreed to three changes in the eligibility for premium assistance services for patients referred to PSI from VBDP. These included ending premium assistance services for patients receiving or eligible for Medicare or Medicaid/FAMIS, ending premium assistance for patients whose bleeding disorder care was less than \$25,000 annually and requiring patients to access group health insurance if the benefits were equal to or greater than those offered by Open Enrollment or Guarantee Issue policies in Virginia. Capping annual premium assistance to \$11,000 had already been adopted by PSI. With those changes, VBDP did meet its budget in FY09.

Jan also thanked the center social workers and PSI in participating in case management phone calls, in assisting patients to enroll in Medicare advantage plans and in collaborative efforts with ACCESS to coordinate disability determination.

A review of the current VBDP/PSI clients as of 1/2010 was presented. Forty-one percent were on employer-based policies; 24% on conversion policies (two with \$100,000 annual caps) and 36 % on open enrollment policies. Conversion and open enrollment policies tend to have the highest premiums. Jan then reviewed the status of the 22 of 39 patients who transitioned off of services. Fifty-nine percent of the patients transitioned to employer-based policies, Medicare advantage policies or were eligible for or also receiving Medicaid/Medicare. Nine percent died. The remaining patients either were unable to pay the family portion of the premium and became uninsured, were incarcerated or had low utilization of bleeding disorder services and went through state hospital financial screening and compassionate use programs. Sheila asked if anyone went without care, and Jan reported that to her knowledge patients were still able to access care and compassionate medication programs.

Next Jan discussed the length of time on service for the remaining patients on PSI services. Twenty-five percent have been on service between 5-8 years. Nineteen percent have been on service over 8 years, leaving 56% on service less than five years. Kate Lynch mentioned that the intent of this program is to be a safety net and that we need to encourage patients to transition off service. Gail mentioned that low interest loans for such patients might be a better alternative. Eric suggested that we collect additional

information, specifically, where patients receive factor after transitioning off service, where do they receive medical care and where patients referred to PSI originate (ie are these pediatric patients transitioning to adult care. Craig agreed that information on intake and transition is helpful.

Jan also discussed the need for a policy related to the waiting list for PSI premium assistance. She discussed some diagnostic and insurance characteristics of the current waiting list and asked if the priority for referral should be based on date on list, utilization, compliance or other criteria and if new referrals should have a time limit for assistance.

Recommendation: The HAB recommended the creation of a subcommittee to consider possible policies to encourage transition off of PSI/VBDP premium assistance services and to consider policies for the waiting list. Eric, Lauren Dunn and Tracy Cleghorn agreed to serve on the subcommittee.

The HAB also reviewed and agreed to the POF guidelines, pending the recommendations of the subcommittee.

VI. State and Federal Budget Issues

Jan mentioned that Becky Bowers-Lanier from the Virginia Hemophilia Foundation (VHF) was not able to join the HAB today due to a family emergency. Jan presented three aspects of the current budget issues: federal funding for HTC's, Virginia's biennial budget and its impact on Medicaid and VBDP, and the status of federal health reform.

With regard to federal funding, Jan mentioned that the Centers for Disease Control and Prevention through the Region III Core Center fund Virginia HTC's about \$100,000 annually. The FY2011 Obama Budget Proposal changes the funding structure for blood disorders. The proposal eliminates line item funding for any one program and realigns funding for a public health approach to blood disorders, including funding for epidemiological research/surveillance, lab monitoring and prevention research and awareness for a national framework for prevention of birth defects and complication from blood disorders. Jan shared that the Virginia HTC's could lose about 60% of their federal funding. The HTC's have been hit with funding cuts from the Bureau of Maternal and Child Health in recent years. Also some plans for health care reform include decreased reimbursement for Disproportionate Share Hospitals (DSH) and Medicaid providers. The goal of health care reform is to decrease the rate of uninsured patients; however this transition may not be realized by the time the DSH hospital funding has been cut. The three Virginia HTC's are DSH hospitals, serving large Medicaid populations. Eric shared the concerns of CHKD as an institution dealing with such large potential revenue decreases and the concerns for the existence of HTC's as such institutions. Jan mentioned that none of the Virginia HTC's have an active 340B program, making them dependent upon federal and state funding. Eric suggested that HTC's need to emphasize their role in disease management, stressing the outcomes of healthier and more productive citizens through the HTC services and the importance of the HTC for cost-containment. Gail agreed that HTC's need to document their cost-effectiveness. Kelly mentioned that VHF

in conjunction with NHF at Washington Days has shared with legislators their concerns about HTC funding.

Recommendation: The HAB recommended that a letter be written to the Virginia delegation to the federal government regarding their concerns about possible decreased CDC funding and emphasizing the cost-effectiveness of HTC care.

Jan next discussed Becky's presentation on the Virginia Biennial Budget Bill and the concerns that the Federal Assistance to Medicaid Programs (FMAP). Without the extension of FMAP, significant cuts to the eligibility for Medicaid and reimbursement to Medicaid providers will be realized. The latter may affect access to care. Becky's presentation noted that the next step is that the Senate amendment of the American Workers, State and Business Relief Act of 2010 goes to the House soon. Rachel Cain from DMAS noted that there are no current plans to decrease factor concentrate reimbursement at DMAS. Jan did note that other budget issues that may impact the bleeding disorders community including reduced funding for Children's Health Insurance Program of Virginia and reductions in the Comprehensive Services Act, which has served approximately 7-10 patients in the past several years. Jan did note that no immediate reduction in VBDP funding has been noted. VHF made VBDP funding a legislative priority in 2010.

Jan opened the discussion about health care reform, but noted that it was premature to really discuss the implications of the law that just passed yesterday. Gail noted that the program needs to keep an eye on the changes to health insurance. Eric again emphasized the need to document outcomes of HTC care, especially in terms of cost-savings and disease management.

VII. Life Insurance and Inherited Bleeding Disorders

Jan briefly reviewed the discussion at the meeting last year. Many patients with inherited bleeding disorders are excluded from life insurance benefits or receive extremely high ratings. These high rating scales may also include patients with mild disease and no comorbidities. In 2008, the HAB recommended that the VBDP request the CDC to do further analysis of mortality rates/life expectancy rates. Jan had several conference calls with Mike Soucie, PhD, epidemiologist in the Division of Blood Disorders, National Center on Birth Defects and Developmental Disabilities. Dr. Soucie conducted further analysis of the data collected as part of the "Mortality among males with hemophilia: Relations with source of medical care." (J. Michael Soucie, Rachelle Nuss, Bruce Evatt, Abdou Abdelhak, Linda Cowan, Holly Hill, Marcia Kolakoski, Nancy Wilber, and the Hemophilia Surveillance System Project Investigators). Dr. Soucie used the same data from that first analysis and removed all subjects with a medical record indicating that they had a positive test for hepatitis C during the period. The results were similar to those obtained when removing patients with a positive test for HIV. The life expectancy for those without positive tests for HIV and Hepatitis C from the data for 1997 was 72.5 years which is very similar to the life expectancy of the U.S. male population in 1997 of 73.6 year. Dr. Soucie recommended that for these purposes, he

would still quote the first estimate reported in the study since it has been peer-reviewed and is in the literature. It could also be mentioned that the preliminary results from the later period and reference it as unpublished CDC data. He does plan to try to extend the data to later periods using mortality data reported as part of UDC and work to get it in the literature.

The HAB was very appreciative of the analysis and encouraged by ongoing work to extend the data to later periods.

VIII. Von Willebrand Disease (vWD) Outreach to Adolescent Females in Family Planning Clinic

Jan presented a new initiative that the VBDP in conjunction with the VCU HTC will be undertaking with local health district family planning (FP) clinics. The program goal is to provide education and outreach regarding vWD to local health department clinics. Jan noted that the project has been funded in part by a Children's Miracle Network minigrant through VCU. Jan thanked Kim Stewart, Kate and Mindy Nolte as members of the subcommittee for their guidance and work on the project. To date, one webinar was conducted in October of 2009; unfortunately it was not well attended. Jan noted that the local districts were in the middle of H1N1 vaccinations and that another webinar is planned for this spring. She thanked Kelly from the VHF for providing funding for the webinar. She did note that the educational provider brochures have been purchased along with some Spanish educational tools for young girls in the clinic. The screening tool, educational fact sheet and powerpoint presentation have been added to the VBDP website.

Craig Smith added that he would be happy to help local health districts understand the importance of this initiative. Eric added that further education in medical provider trainings would also be helpful. Gail shared her concerns that patients who are screened at the local health district and referred to their local health care provider may not get an appropriate workup. She noted that HTCs need to be a resource for the local providers in making the diagnosis.

Recommendation:

The Board recommended the further work on this project, with the support of the local health district directors.

IX. Obesity and Bleeding Disorders

As a follow up to the presentations at the December 2008 HAB meeting on Obesity, an informal stakeholders group met in the fall to discuss the role of the VBDP and HTCs in obesity prevention and treatment. Jan thanked Laura Duncan, Janet Willis from the VCU HTC and Candice for their work. She also thanked Ann McClellan from the CDC for their data analysis reporting to the HAB and Megan Ullman from the University of Texas for sharing her preliminary work using data collected by the HTCs and reported to the CDC. Jan presented the CDC data, demonstrating that 31 % of the 185 Virginia children

with hemophilia studied were overweight and obese. Although the data was not analyzed by a statistician, it does not appear that significant differences among regions, ethnicity or insurance coverage. The percentage of children with mild hemophilia with normal weight was higher than that of children with severe or moderate hemophilia. Of the 176 adults in the reported data, 62% were overweight or obese. The percentage of adults who were obese did not appear to be affected by severity of disease.

Jan also presented preliminary work of Ms. Ullman who also used the CDC data. This project examined CDC Universal Data Collection project participants to determine if overweight and obesity are associated with the treatment patterns of hemophilia patients.

- 1/2 of the sample (all ages) was above normal weight.
- One-fifth of children and teens were obese.
- 27% of adults ($BMI \geq 30$)
- Among adults, the following strong associations ($P < 0.001$) were found:
 - $BMI \geq 25$ was positively associated with mild disease
 - Among all severities, overweight and obese patients were less likely to infuse at home than were those of normal weight
 - $BMI \geq 25$ was positively associated with use of a MCP for infusion and negatively associated with self-infusion

Gail did note that the population in the sample may not reflect the hemophilia population as patients must consent to have their data reported.

Jan discussed some possible roles of the VBDP in addressing obesity, including interventions in comprehensive clinics, collaboration with VHF on educational programs and developing/acquiring resource and referral information. Eric noted that prevention target should focus on the very young since the tipping point for obesity has been reported as two years of age. Kate mentioned their center's frustration with a local program that did not have good patient outcomes. She also mentioned that cost can be a barrier to eating healthy. Eric also mentioned the importance of the HTCs working with obesity programs to modify as necessary for patients with inherited bleeding disorders and suggested that monitoring outcomes is critical. Kelly mentioned that the VHF is committed to further work in this area, even after the end of the YMCA funding through NHF. Paul Brayshaw commented on the importance of the role of mentors in this effort. Sheila underscored the importance of this public health issue.

The HAB recommended that a subcommittee be established to consider strategies to address obesity in this population. Laura Duncan, Tracy Cleghorn, Sheila Elliott and Kate Lynch agreed to serve on the subcommittee. Kelly Waters asked that the group collaborate with VHF.

X. Public Comment

Jan distributed a citizen's petition to the Federal Drug Administration to include patients with inherited bleeding disorders in clinical trial for Hepatitis C treatment. Sandy

Qualley from Hemophilia of the Capitol Areas asked the HAB to be aware of this issue. No public comment further was noted. The meeting was convened at 1:30 pm.